

ANNEX I

ACCELERATED TEST FOR STORAGE STABILITY OF PH

The Xueshuantong injection (Samples A1 to A8) and the iv injection prepared according to the present invention (Samples B1 to B8) were encapsulated and stored at a constant temperature of 25°C, respectively. At the time of 0, 1, 2, and 3 months, the pH values of the samples were measured. The results were listed in Tables 1 and 2 below.

Table 1. Accelerated Test for Storage Stability of pH of Xueshuantong Injection

Sample No.	Time (months)			
	0	1	2	3
A1	5.84	5.30	4.69	4.18
A2	5.93	5.42	5.17	4.60
A3	5.98	5.50	5.02	4.54
A4	5.72	5.26	4.90	4.08
A5	5.87	5.37	4.82	4.14
A6	5.69	5.08	4.76	4.00
A7	5.74	5.12	4.88	4.02
A8	5.80	5.44	5.10	4.23

Table 2. Accelerated Test for Storage Stability of pH of the IV Injection Prepared in Accordance with the Present Invention

Sample No.	Time (months)			
	0	1	2	3
B1	6.36	6.22	6.16	6.10
B2	6.48	6.34	6.16	6.16
B3	6.56	6.50	6.52	6.48
B4	6.56	6.48	6.42	6.36
B5	6.34	6.24	6.15	6.09
B6	6.42	6.38	6.30	6.29
B7	6.48	6.48	6.40	6.32
B8	6.39	6.26	6.32	6.20

As shown in Tables 1 and 2, the pH of Xueshuantong injection declines remarkably over time, especially after stored for 2-3 months, the pH even declines to a value which does not comply with the Chinese Medicine standard as taught in the last paragraph of the description. It can be seen that the Xueshuantong injection has poor storage stability. In contrast, the IV injection prepared in accordance with the present invention exhibits superior storage stability. In particular, the product of the present invention exhibits a pH decrease of less than 0.3 and the pH of the injection remains

always within the Chinese Medicine standard. Thus, the iv injection of the present invention was substantially improved in terms of storage stability of pH in comparison to the prior art.

Conventional Xueshuantong injections are primarily used for the treatment of acute ischemic cerebrovascular diseases, cerebral thromboses, cerebral infarctions, temporary cerebral hemorrhages, cerebral hemorrhage sequelae; obstruction of the central retinal vein, centralis serosa, bleedings of anterior chambers of eye, bulbar conjunctiva and vitreous body; coronary heart diseases, pulmonary heart diseases; hyperlipemia; and the like. The results of clinic experiments indicate that the stability of products will be substantially affected if the pH of the product decreases. Acidic injections when administered into human bodies tend to cause untoward effects including erythra; pruritus; red papulae on head and face, trunk and inner sides of limbs; and the like; even the patients may have a shock.

Thus, the product of the present invention having better storage stability of pH should not be obvious over the prior art including Xueshuantong injection and produce an undesired effect.